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09/817,251	03/27/2001	Hisao Hiramatsu	Q63803	8044
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SUGHRUE-265550				SOOHO, TONY GLEN
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	09/817,251	HIRAMATSU ET AL.
	Examiner Tony G. Soohoo	Art Unit 1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 July 2007 AND 06/18/2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,4,5,7,11,12,14,15,17,19,21 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4,5,7,11,12,14,15,17,19,21 and 24-277 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Claim interpretation

1. Claims 19 and 21 point out the use of the method in an apparatus. It has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961). According the mere intention that the method to be used by a particular device does not provide any patentable manipulative step to the claimed method.

19. (previously presented): The method according to claim 1, which is used in an inspection apparatus.

Claim 20. (canceled).

21. (previously presented): The method according to claim 11, which is used in an inspection apparatus.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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3. Claims 1, 3-6, 7, 11, 13-16, 17, 19, and 21-27 are rejected under 35 U.S.C. 103(a) as obvious over JP 62-184357 in view of Knobel 5482863 and in view of and in view of Makino et al 5555767.

The JP 62-184357 (JP '357) reference discloses as seen in figures 1 (i) through IV), as described in the supplied translation an automatic controlled repeated sucking and discharge of fluid on to the surface of the remaining liquid in a container to provide stirring. It is noted that the nozzle initially is empty thereby having air in the nozzle before the sucking step.

The translation states (emphasis by examiner added in BOLD):

First, the liquid A is preliminarily present on the bottom of the container (4) in Figure 1 (i). The pipette (1), which has already suctioned the liquid B, becomes inserted into the container (4) in this state, and the liquid B is then extruded. The liquid A and liquid B therefore become mutually mixed, although a sufficient agitation state has yet to arise.

In Figure 1 (ii), the distal end of **the pipet becomes lowered and then immersed underneath the liquid surface of the liquid mixture A + B**. A certain volume (e.g., a half of total volume) is then suctioned.

Next, in Figure 1 (iii), the distal end of **the pipet becomes elevated in a state where the liquid mixture remains suctioned and then positioned above the liquid surface of the liquid mixture stocked within the container**. The liquid within the pipet becomes extruded in this state.

In Figure 1 (iv), furthermore, the state of Figure 1 (ii) becomes restored at the distal end of the pipet. In other words, **the pipet distal end is lowered underneath the liquid surface in preparation for suction**.

The pipet descension & suction and pipet ascension & extrusion actions discussed above are **repeated within a single container**.

F. Functions

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The liquid within the container becomes sufficiently agitated physically as a result of the repetitions, via an interface provided by the liquid surface of the liquid within said container, of pipet descension & suction and pipet ascension & extrusion actions. The agitation is predicated on liquid countercurrents arising as a result of suction and on **the collision of the extruded liquid with the liquid plane, etc.**

As supported above in a finding of fact, the JP '357 has shown within the prior art, method steps which include a steps of

- 1) sucking a part of a liquid [A +B] into a nozzle [via pipette 1] from a liquid containing container [4], the step of
- 2) discharging the sucked liquid from the same nozzle directly above the surface of the liquid thereby to stir the liquid [fig 1 (iii), the step of
- 3) whereby the sucking and discharging are automatically controlled [via control 12], and the step of
- 4) conducting the procedure plural times.

The JP '357 reference discloses all of the recited subject matter as defined within the scope of the claims with the exception of and additional step of whereby, after the JP'357's step of raising the pipette when positioned above the liquid surface of container, the additional step of moving the pipette at horizontally different position from the sucking position is made, prior to the JP'357's step of the extruding the pipette's contents back into the surface of liquid in the container having an inclined wall of increasing with height toward the outside of the container.

In other words, the only differences are that 1) one moves the pipette to a different position just before ejecting the contents of the pipette and 2) ejecting contents from the pipette toward an inclined wall of the container.

The reference to Knobel 5482863 (Knobel '863) teaches that it is desirable to discharge a liquid into a container at two different positions thereby creating two vortex flows, column 3, lines 47-64, so as to enable the solid phase to be suspended exclusively by injection of reagent, thus avoiding the need for a subsequent shaking operation.

Knobel states (emphasis by examiner added in BOLD)::

(12) The inventive process is suitable for other applications in addition to suspending particles deposited at diametrically opposite regions on the wall, relative to the central longitudinal axis. After a portion of the predetermined volume of reagent liquid has been pipetted into the reaction vessel in a first position, the pipetting needle can be rotated to any desired second position at a distance from the central longitudinal axis of the reaction vessel, where the deposited particles are suspended by adding the remaining part-volume of reagent liquid. **In addition, a solution already in the reaction vessel can be efficiently mixed with other solutions.**

(13) A main advantage of the present invention is that **addition of reagent liquid at two different positions in a reaction vessel results in a flow therein, enabling the solid phase to be suspended exclusively by injection of reagent, thus avoiding the need for a subsequent shaking operation.** In analytical equipment, the inventive device can produce an optimum suspension of particles during the addition of reagent, simply by choosing a suitable program for actuating the pipetting needle, so that a maximum number of samples can be processed per unit time.

And column 4 lines 32-40:

(20) FIG. 3 shows the pipetting needle 18 in a first position at a distance *e* from the central longitudinal axis 22, where a part of the predetermined volume of reagent liquid 21 is injected. The resulting vortex 24 is diagrammatically shown.

(21) FIG. 4 shows the pipetting needle 18 in the second position at a distance *e* from the central longitudinal axis 22, where the rest of the predetermined volume of reagent liquid 21 is injected. The resulting vortex 25 is diagrammatically indicated, showing the reverse direction of rotation.

Also, on column 4, lines 52-64, the reference teaches that the distance of the position whereby the pipet is moved for dispensing may be readily varied:

(25) The invention has been described in terms of its preferred embodiments. However, upon reading the present specification various alternative embodiments will become obvious to those skilled in the art. For example, **travel distance** **(e) can be readily varied**, as can the type of pipetting device, type of reaction container, processing station, etc.

Accordingly, with regards to *moving the pipette to a different horizontal position just before ejecting the contents of the pipette*, in view of the teaching of the Knobel '863 reference that it is desirable to inject the fluid from the pipette from two different positions thereby creating advantageous vortex flow action thus avoiding the need for a subsequent shaking operation to produce a desirable mixing effect, it is deemed that it would have been obvious to one of ordinary skill in the art to provide for the method taught by the JP '357 reference with an additional step of moving the pipette to a

different location prior to ejecting the fluid from the pipette so that addition vortex flows are produced in the container in order to more effectively mixing and reduce the need for shaking the container for adequate mixing effect.

With regards to the discharging of the sucked liquid toward an *increasing* inclined container wall, the Makino et al reference shows examples which a pipette may be used to mix liquid in a container which may have vertical walls figure 2 or alternately with walls with an increasing incline as see in figure 3 or 5, column 5, lines 26-32. Accordingly, absent any unexpected results, it is deemed that it would have been obvious to one of ordinary skill in the art to substitute for the type of container of the type used by JP '357 with a commonly known functional equivalent container which may hold materials for a pipette, such as the type of container having walls at an incline as shown by Makino et al so that liquid dispensed by the pipette may more easily flow down from the sidewalls for good stirring performance.

With regards to issues of the sucking and dispensing positions, the prior art as applied discloses all of the recited subject matter as defined within the scope of the claims with the exception of discharging the liquid a position limited in a horizontally external position to the sucked position or sucked near the center of the container, or sucked at a deepest position.

Knobel reference is cited as evidence that one may move a nozzle to various positions for sucking or dispensing a pipette for mixing. Without undue

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experimentation, it is deemed that it would have been obvious to one of ordinary skill in the art to modify, vary, or limit the positions of the sucking and discharge points any appropriate position in the container so that mixing is optimized by a more effective suction flow or vortex flow within the container, and provide an automated step to reproduce such a repetitive process by a machine.

With regards to claims 7 and 17 and the particular material in which the method of stirring is to be worked upon, it is noted that the claim is directed to a method for stirring a liquid. The instant invention is not a particular method of "processing blood". Since the recited intended use of the method of stirring is "for.. a liquid", the type of liquid is deemed as an environment of the stirring method. The manipulation of fluid as presented by the JP '357 as modified by the references above is fully capable of acting upon any liquid including that of blood.

Whereby the type of fluid (i.e. blood, water, high solids liquid suspension) to be used in the stirring manipulation does not perfect or affect the stirring manipulation in a positive sense of fluid dynamics, little patentable distinction is afforded to the use of blood in perfection of the stirring. Nonetheless, it is deemed that it would have been obvious to one of ordinary skill in the art to use the method of JP '357 as modified whereby the processing of blood by a pipette is old and well known so as to provide a convenient manner to mix blood by a pipette.

With regards to claims 19 and 21, the recitation of the use of the method in an inspection apparatus does not point out a positive manipulative step in the perfection of stirring a fluid thereby has been afforded little patentable distinction, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. Ex parte Pfeiffer, 1962 C.D. 408 (1961)

4. Claims 2 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 62-184357 in view of Knobel 5482863 as applied to claims 1, 11 respectively above, and further in view of JP 64-27626 (all cited previously).

JP 62-184357 in view of Knobel 5482863 discloses all of the recited subject matter as defined within the scope of the claims with the exception of the step of discharging air. It is noted that the nozzle initially is empty thereby having air in the nozzle before the sucking step.

The JP 64-27626 (JP '626) reference teaches that air maybe sucked into a discharge nozzle and discharged with the sample into the container causing air bubbles to further mix the fluid component.

Accordingly, it is deemed that it would have been obvious to one of ordinary skill in the art to further provide the JP '357 as modified above, an additional step of sucking

in air into the pipette so that air may also be discharged with the fluid components to provide bubbles to cause further mixing and stirring.

Response to Arguments

5. Applicant's arguments filed 06/18/2007 have been fully considered but they are not persuasive.

6. Applicant argues with regards to the combination of the teachings of JP 62-184357357 with the Knobel 5,482,863, JP 64-27626 and Makino et al 5,555,767.

7. In the following arguments:

On page 8, of the remarks filed 09/817,251 applicants alleges that evidence to unexpected results shown by Applicant's Rule 1.132 Declaration filed December 24,, 2003 supports that it would have been obvious to one of ordinary skill in the art to combine the references. Applicant states:

Applicants respectfully submit that the unexpected results detailed in Applicants' Rule 132 Declaration filed December 24, 2003 would not have been obvious to one of ordinary skill in the art. Specifically, the liquid used in the experiment is the whole blood of a normal subject.

8. In response, it is noted that the tests are directed to the stirring processing efficiency of hemolysate absorbance in whole blood. In contrast, the instant invention is directed to stirring fluids. The data results, while pertinent to a particular measurement of the degree of absorbance of the homolysate within whole blood, does not measure

results to the instant invention of a degree of mixing of a fluid. Conclusions gleaned by the results of the tests do not in provide a trend applicable to liquids in general as encompassed by the genus claim. Refer to the MPEP 716.02,

716.02(d) Unexpected Results Commensurate in Scope With Claimed Invention [R-2]

Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the “objective evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support.” In

other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980)

9. Applicant further asserts

The method set forth in JP '357 does not sufficiently stir a liquid with a high solid content as shown in conditions B and E of the experiment detailed in Applicants' Rule 132 Declaration filed December 24, 2003. Namely, the method cannot be used for stirring of a liquid with a high solid content.

10. With regards to Applicant's further discussion of the “solids content” of the invention and the prior art deemed immaterial to the instant claimed invention. The

claims do not particularly state a manipulation of the liquid with a particular solid content and solid content percent.

11. Applicant allege

On the other hand, the method as set forth in Knobel can stir a liquid with an extremely low solid content as is evident from the diagrams as set forth therein. In contrast, using the method claimed in claims 1 and 11, a liquid with a solid content of 40% or more can be stirred to a level equivalent to that achievable with a touch mixer via suction and discharge of a comparatively small amount of liquid. In other words, the method of claims 1 and 11 is capable of uniform stirring of a high solid content liquid by repeating suction and discharge of a comparatively small amount of liquid automatically over several times. Thus, Applicants submit that it is impossible for those skilled in the art to predict such effect only over JP '357 and Knobel.

Therefore, amended claims 1 and 11 are patentable over the applied art. Claims 2, 4, 5, 7, 12, 14, 15, 17, 19 and 24-27 are patentable at least by virtue of their dependency from amended claims 1 and 11.

12. In response to the general allegation that the instant method claims is more capable of uniform stirring high content liquid, applicant has failed to satisfy the burden of explaining the data evidence in support of non-obviousness. There is no discussion of the data point or particular analysis to the what is gleaned by the raw data points. MPEP states:

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II. < APPLICANTS HAVE BURDEN OF EXPLAINING PROFFERED DATA

"[A]ppellants have the burden of explaining the data in any declaration they proffer as evidence of non-obviousness." *Ex parte Ishizaka*, 24 USPQ2d 1621, 1624 (Bd. Pat. App. & Inter. 1992).

>

13. Furthermore, there is no analysis that differences between of the data of the invention with that of the a prior art method appears to be beyond an expected discrepancy of statistical accuracy of the measurement techniques.

See MPEP 716.02(b)

716.02(b) Burden on Applicant [R-2]

>

I. < BURDEN ON APPLICANT TO ESTABLISH RESULTS ARE UNEXPECTED AND SIGNIFICANT

The evidence relied *>upon< should establish "that the differences in results are in fact unexpected and

unobvious and of both statistical and practical significance.” *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992) (Mere conclusions in appellants’ brief that the claimed polymer had an unexpectedly increased impact strength “are not entitled to the weight of conclusions accompanying the evidence, either in the specification or in a declaration.”); *Ex parte C*, 27 USPQ2d 1492 (Bd. Pat. App. & Inter. 1992) (Applicant alleged unexpected results with regard to the claimed soybean plant, however there was no basis for judging the practical significance of data with regard to maturity date, flowering date, flower color, or height of the plant.). See also *In re Nolan*, 553 F.2d 1261, 1267, 193 USPQ 641, 645 (CCPA 1977) and *In re Eli Lilly*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) as discussed in MPEP § 716.02(c).

>

In fact, the measurements of the prior art of B2:0.6241, C4:0.6364, E5:0.6841 and F3:0.6446 (shaded oval values) appears to be as great as, or greater than, the measured values of the instant invention of A1:0.6243 and D5:0.6579 (shaded square values). Thus, it appears that the evidence shown in table 2 of the declaration supports that there is no out of the ordinary result, or benefit, provided by the instant invention beyond that of the prior art, such that a statement of unexpected and significant results has been gleaned of both statistical and practical significance.

TABLE 2

	Reference	Condition					
		A	B	C	D	E	F
1	0.6497	0.6243	0.6325	0.6236	0.6593	0.5255	0.5899
2	0.6489	0.6255	0.5946	0.4781	0.6652	0.5960	0.1649
3	0.6567	0.6308	0.6241	0.5820	0.6632	0.6219	0.6446
4	0.6466	0.6405	0.6169	0.6364	0.6730	0.6648	0.5450
5	0.6511	0.6408	0.6087	0.5924	0.6579	0.6841	0.5178
Mean	0.6508	0.6323	0.6154	0.5825	0.6637	0.6185	0.4944
SD	0.0038	0.0079	0.0145	0.0624	0.0080	0.0625	0.1906
CV	0.58	1.24	2.36	10.72	0.90	10.10	38.56

14. Accordingly, for the reasons discussed above, Applicant has not provided convincing arguments that the JP'357 in view of the prior art references to Knobel 5,482,863, JP 64-27626 and Makino et al 5,555,767 are not a prima fascia obvious over the instant claims.

Conclusion

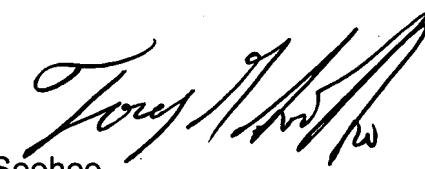
15. The previously cited prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following disclose pipette devices which may repeatedly provide suction and dispensing and may be moved: Miyake et al 5174162, JP 09-297125, JP 09-171024, and JP01-212356, and JP 03-170046. Tanaka 5820824 is of the same family of JP 09 171024 or JP 2002-126985.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tony G. Soohoo whose telephone number is (571) 272 1147. The examiner can normally be reached on 8AM-5PM,Tue-Fri.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Tony G Soohoo

Primary Examiner

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**TONY G. SOOHOO
PRIMARY EXAMINER**